61. A method for treating a subject for an allergic or hypersensitivity condition comprising administering to the subject an effective amount of an agent selected from the group consisting of CtxB, EtxB, or a mutant or derivative thereof that modifies a GM1-associated activity, and is not coupled to an antigen.

62. A method according to claim 61 wherein CtxB is administered.

63. A method according to claim 61 wherein EtxB is administered.

64. A method according to claim 61 which is a treatment for asthma.

65. A method according to claim 61 which is a treatment for asthma comprising administering to the subject an effective amount of EtxB or a mutant of EtxB having the immunomodulatory properties of EtxB.

REMARKS

Claims 20 to 24, 26 to 30, and 40 to 48 were pending in this application prior to entry of the above amendments. All the pending claims were cancelled and replaced by new claims 49 to 65. Because the number and dependency of the cancelled claims exceeds that of those added, no new claim fees are due or presented herewith.

This invention relates to agents such as EtxB which are employed to treat allergic and/or hypersensitivity conditions such as asthma. The originally presented claims 20 to 39 were subjected to a restriction requirement on 5 December 2002, made final in an action dated 21 March 2001. While Applicants still do not agree that the originally presented claim set claimed three inventions, the group I claims (20 to 30, directed to assay methods for identifying useful agents) were elected with traverse and examined. Subsequent research has made it desirable for Applicants to prefer the group III claims

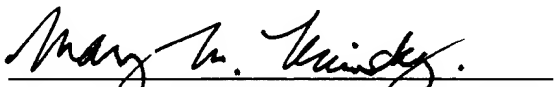
directed to treatment methods. Hence, this amendment is directed to treatment methods accompanied by an RCE.

The new claims track the language of former claims 32 to 39. Claims 49, 56 and 61 are directed to methods of treating an allergic or hypersensitivity condition comprising administering to a subject an effective amount of an agent such as Etx, Ctx, CtxB, EtxB, and mutants or derivatives thereof that bind to GM1, that modifies a ganglioside-associated activity, notably GM1, wherein the agent is not coupled to an antigen, and are supported in the specification on page 10 at lines 1 to 13, on page 12 at lines 25 to 26,. and on page 13 at line 15. Claim 50 adds to claim 49, and claim 58 to 56, the limitation that the agent is capable of blocking an IgE-mediated response, supported in the specification on page 10 at lines 15 to 16. Claims 51 and 57 particularly point out agents that bind to GM1 described in the specification on page 12 at line 23. Claims 52, 53, 55, 59, 62, 63, and 65 add limitations to embodiments comprising Etx, Ctx, CtxB, and EtxB set out in the specification on page 12 at lines 25 to 26. Asthma treatments particularly pointed out in claims 54, 64, and 65 is supported in the specification on page 2 at line 1.

If the undersigned can advance prosecution of this application in any way, please communicate using the information below.

Respectfully submitted,

on 5 April 2002 by



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ABSTRACT

The use of an agent in the manufacture of a medicament to affect an allergic condition and/or a hypersensitivity condition is described. The agent is capable of modulating a ganglioside associated activity. The agent is not coupled to an antigen. The modulation of the ganglioside associated activity affects an allergic condition and/or a hypersensitivity condition.